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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,864	08/29/2003	Heinz Kohler	200-019	1487

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EXAMINER	
TUNGATURTHI, PARITHOSH K	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/652,864	KOHLER ET AL.	
	Examiner	Art Unit	
	Parithosh K. Tungaturthi	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. It is noted that claims of the instant application consist of amino acid sequences within. The applicant is suggested to include the SEQ ID NOs instead of an amino acid sequence.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2 in part and 1, 3, 4, drawn to a method of treating a patient suffering from a debilitating or life threatening disease comprising administering at least one autophilic antibody to the patient in an amount effective to alleviate symptoms of the disease, wherein the disease is malignancy, classified in class 424, subclass 9.1, for example.

II. Claims 2 in part and 1, 3, 4, drawn to a method of treating a patient suffering from a debilitating or life threatening disease comprising administering at least one autophilic antibody to the patient in an amount effective to alleviate symptoms of the disease, wherein the disease is auto-immune disorder, classified in class 424, subclass 9.1, for example.

III. Claims 2 in part and 1, 3, 4, drawn to a method of treating a patient suffering from a debilitating or life threatening disease comprising administering at least one autophilic antibody to the patient in an amount effective to alleviate symptoms of the disease, wherein the disease is

transplantation rejection, classified in class 424, subclass 9.1, for example.

IV. Claims 2 in part and 1, 3, 4, drawn to a method of treating a patient suffering from a debilitating or life threatening disease comprising administering at least one autophilic antibody to the patient in an amount effective to alleviate symptoms of the disease, wherein the disease is Alzheimer's disease or other neuro-degenerative condition, classified in class 424, subclass 9.1, for example.

V. Claim 5, drawn to a method of potentiating apoptosis of selected cells in a patient comprising administering to the patient a first autophilic antibody-peptide conjugate and a second antibody directed to the autophilic peptide itself, classified in class 424, subclass 9.1, for example.

VI. Claims 6-10, drawn to a method of producing an autophilic antibody by chemical or genetic engineering techniques, wherein the autophilic antibody contains a T15 autophilic peptide, classified in class 435, subclass 69.1, for example.

VII. Claim 11, drawn to a method of formulating an autophilic antibody composition so as to reduce or mitigate dimerization, classified in class435, subclass 69.1, for example.

VIII. Claim 12, drawn to a method of expressing an increased degree of apoptosis in an *in vitro* assay, classified in class 424, subclass 277.1, for example.

IX. Claim 13, drawn to a method of identifying an autophilic antibody candidate for use in humans comprising administering the autophilic antibody to SCID or nude mice having human tumor xenografts, classified in class 424, subclass 9.1, for example.

X. Claims 14 and 15, drawn to a method determining a peptide sequence for enhanced for noncovalent autophilic coupling between antibody molecules, classified in class 435, subclass 7.1, for example.

XI. Claims 16 and 17, drawn to a method of producing an autophilic antibody by chemical or genetic engineering techniques, wherein the autophilic antibody contains a modified T15 autophilic peptide sequence that further potentiates the ability of the modified autobody to crosslink once bound to a target antigen relative to the unmodified antibody, classified in class435, subclass 69.1, for example.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-XI are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. In the instant case, Group I-IV recites a method of treating a patient suffering from a debilitating or life threatening disease comprising administering at least one autophilic antibody to the patient in an amount effective to alleviate symptoms of the disease, wherein the disease is malignancy, auto-immune disorder, transplantation rejection and Alzheimer's disease or other neuro-degenerative

condition, respectively. Group V recites a method of potentiating apoptosis of selected cells in a patient comprising administering to the patient a first autophilic antibody-peptide conjugate and a second antibody directed to the autophilic peptide itself, Group VI recites a method of producing an autophilic antibody by chemical or genetic engineering techniques, wherein the autophilic antibody contains a T15 autophilic peptide, Group VII recites a method of formulating an autophilic antibody composition so as to reduce or mitigate dimerization, Group VIII recites a method of expressing an increased degree of apoptosis in an *in vitro* assay, Group IX recites a method of identifying an autophilic antibody candidate for use in humans comprising administering the autophilic antibody to SCID or nude mice having human tumor xenografts, Group X recites a method determining a peptide sequence for enhanced for noncovalent autophilic coupling between antibody molecules, Group XI recites a method of producing an autophilic antibody by chemical or genetic engineering techniques, wherein the autophilic antibody contains a modified T15 autophilic peptide sequence that further potentiates the ability of the modified autobody to crosslink once bound to a target antigen relative to the unmodified antibody, classified in class, subclass. Thus, each group differs in method objectives, method steps and parameters and in the reagents used. Further, each group is unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has different mode of operation. Each invention further performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for detection differ significantly for each of the materials. The examination of all groups

would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions I-VIII are separate and distinct in having different method steps and different endpoints and are patentably distinct.

5. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Parithosh K. Tungaturthi, Ph.D.
Ph: (571) 272-8789

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER